

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 7, 10, 16, 20 and 24-28 are amended to clarify what is intended by the terms “fat metabolism” and/or “protein metabolism.” Support for these amendments can be found in the Specification at pages 8-9, paragraphs [0035] to [0038]. No new matter is added by this amendment.

Claim 3 is amended to correct a clerical error, deleting a superfluous “the.”

Claims 1-38 remain pending.

***Information Disclosure Statement***

The Office Action alleges that the Information Disclosure Statement (IDS) submitted 13 June 2006 is not in compliance with 37 C.F.R. § 1.97, because “the art does not qualify as prior art.” Accordingly, the IDS was not considered. While Applicant thanks the Examiner for his determination, nothing in 37 C.F.R. § 1.97 permits refusal to consider an IDS on this basis. Applicant submits that the IDS fully conforms to the requirements of 37 C.F.R. § 1.97 and requests that the Examiner consider the cited references, acknowledging his consideration by initialing the PTO Form SB/08 accompanying the IDS submitted 9 June 2006.

The requirements of 37 C.F.R. § 1.97 are provided below:

**§ 1.97 Filing of information disclosure statement.**

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

(b) ...

(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final

action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

(1) The statement specified in paragraph (e) of this section; or

(2) The fee set forth in § 1.17(p).

(d) ...

(e) ...

(f) No extensions of time for filing an information disclosure statement are permitted under § 1.136. ...

(g) An information disclosure statement filed in accordance with section shall not be construed as a representation that a search has been made.

(h) The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

(i) If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office.

Subsection (a) of 37 CFR § 1.97 presents two requirements. First, it requires that the IDS be in compliance with 37 C.F.R. § 1.98. Applicant will address this requirement below. Second, it requires that the IDS be submitted to meet the timing requirements of subsection (b), (c), or (d). The IDS submitted 9 June 2006 met the requirements of subsection (c) by being filed before the mailing date of a final action, a notice of allowance or another action that otherwise closes prosecution in conjunction with payment of the fee under 37 C.F.R. § 1.17(p). Indeed, Applicant notes that a later filed IDS was considered by the Examiner and art from that IDS was cited in the present Office Action. Applicant notes that no extension of time was taken to submit the IDS, thus meeting the requirements of subsection (f). Applicant acknowledges subsections (g) and (h), which indicate that an IDS is not to be construed as a representation that a search has been made or as an admission that the information cited in the statement is, or is considered to be, material to patentability.

Subsection (i) permits the Office to refuse to consider an IDS only if it does not comply with 37 CFR § 1.97 or 1.98. As discussed above, the IDS submitted 9 June 2006 met all the requirements of 37 CFR 1.97. 37 CFR § 1.98 dictates the formal requirements of content of the

information disclosure statement. Subsection (a) requires (1) a list of all patents in a form identifying the application in which the IDS is being submitted and certain headings and columns; (2) legible copies of all foreign patents, unpublished U.S. application and each non-patent reference and (3) certain requirements for non-English references. The IDS was submitted in the proper form, on a modified PTO Form SB/08. Legible copies of all references were provided to the Office. All of the cited references were in English. Therefore the requirements of 37 CFR § 1.98(a) were met. Subsection (b) provides the information, *e.g.*, author, title and date, that must be submitted to identify the patent or non-patent reference. Complete citations for the art were provided. Subsections (c) and (d) excuse an applicant from submitting copies of patents or publications that are substantially cumulative or that were submitted in a parent application. As each of the cited references were physically submitted neither subsection affects the IDS submitted 9 June 2006.

Accordingly, Applicant submits that the Information Disclosure Statement submitted 9 June 2006 fully complied with the requirements of 37 C.F.R. §§ 1.97 and 1.98. Applicant requests that the Examiner consider the references cited and acknowledge his consideration by initialing the PTO Form SB/08 that accompanied the IDS.

### ***Duplicate Claims***

The Office Action alleges that claims 13 and 14 are duplicates, based on the interpretation of the term “similar” provided at page 20 of the Office Action dated 10 August 2005. The Examiner asserts that Applicants have acquiesced to the stated interpretation.

Applicant strongly disagrees. Indeed, the Examiner’s interpretation of the meaning of “similar” is contrary to the definition provided by him at page 19 of the Office Action dated 10 August 2005 and, more importantly, contrary to the interpretation that any reasonable person, skilled in the art or otherwise, would assign to the term “similar.” The definition provided by the Examiner is as follows:

**Similar:** Related in appearance or nature; alike although **not identical**.

From these statements, the Office Action concludes that “similar” equals “not identical”. This interpretation of “not identical” requires one to ignore the remainder of the definition, *i.e.*, “related in appearance or nature, alike.” Any person of ordinary skill in the art would recognize that two things may be so “different” as not to be considered “similar.” Accordingly applicant submits that claims 13 and 14 are not identical – rather they have overlapping scope. Not all defects that are different are necessarily similar, even if all defects that are similar are “not identical.”

### ***Claim Interpretation***

The Office Action states that in view of the meaning of “simulation”, the terms “representing”, “representation” and their functional equivalents are interpreted as a mathematical function which is integrated. Applicant accepts the Examiner’s interpretation with one exception. Claim 23 refers to the term “link representation.” This claim explicitly recites

a link representation from a set of predefined link representations, each predefined link representation in the set of predefined link representations being associated with a different mathematical relationship

As used herein, the term “link representation” refers to the graphical illustration of a mathematical relationship. See in particular, paragraphs [0060] to [0082], which describe an exemplary illustration system, including such links, in detail. Accordingly, while a simple “representation” can be interpreted as a mathematical function capable of being integrates, a “link representation” is a graphical illustration of such a simple “representation.”

### ***35 U.S.C. § 102(e)***

**Claims 1-9, 24 and 29-32** stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,582,366 to Porumbescu (hereinafter “Porumbescu”). In order to anticipate a claim, a single reference must, explicitly or inherently, disclose each and every element of a

claim. Applicant submits that Porumbescu does not disclose every element of the present invention as claimed. In particular, the cited reference does not disclose a simulation of multiple macronutrient metabolism in view of the amendment of claims 1, 7 and 24 to clarify what is intended by the terms “fat metabolism” and “protein metabolism.”

While Porumbescu contemplates that consumption of fat, protein and carbohydrate will have different effects on blood glucose levels, this reference merely describes a simple equation to account for a delay in the effect of fat or protein consumption on blood glucose levels by assigning these macronutrients to compartments with an extended time course of exogenous glucose (see column 7 of Porumbescu). This is not a representation of *metabolism* of fat or protein. As discussed in the Specification at page 8, paragraph [0035], metabolism is not merely a straight transition of fat or protein to glucose, delayed or not. Rather, metabolism of a macronutrient includes accounting for the digestion and absorption of the macronutrient, as well as the appropriate associated hormonal responses. Accordingly, claims 1, 7, and 24 are amended to specify that a representation of fat metabolism must include a representation of at least one biological process selected from the group consisting of regulation of adipose tissue uptake of free fatty acid, regulation of adipose tissue lipolysis, regulation of adipose tissue triglyceride esterification, hepatic lipoprotein regulation, muscle free fatty acid uptake, and muscle free fatty acid utilization. A representation of protein metabolism must include a representation of at least one biological process selected from the group consisting of production of amino acids from carbohydrate in muscle, hepatic gluconeogenesis from amino acid substrate, oxidation of amino acids in muscle, oxidation of amino acids in liver, and regulation of skeletal muscle protein turnover in response to a stimulus selected from activity, exercise, fat mass, dietary composition, and insulin.

Since Porumbescu merely treats fat and protein metabolism as a delayed transition directly to glucose without any consideration for the actual mechanism of digestion and absorption of the nutrients this reference cannot anticipate the present invention. Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 102.

**35 U.S.C. § 103**

**Claims 10-18 and 34** stand rejected under 35 U.S.C. § 103 as being rendered obvious by Porumbescu in view of Jonathan Betz Brown, et al. *Diabetes Res. Clin. Prac.* 2000, 50 (Suppl. 3):S15-S46 (hereinafter “Betz-Brown,” to distinguish from U.S. Patent No. 5,956,501 to Brown, referred to as “Brown” is previous Amendments and Office Actions). Claims 10 and 16 are amended to clarify what is intended by the terms “fat metabolism” and “protein metabolism.”

To establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- (2) there must be a reasonable expectation of success.
- (3) the prior art references, when combined, must teach or suggest all the claim limitations.

Applicant submits that the prior art references, when combined, do not teach or suggest every element of the claims, and thus do not render the claimed invention obvious. As discussed above, Porumbescu does not disclose any mechanism by which fat and protein is digested and absorbed, nor does this reference contemplate representing any of the myriad biological processes involved in fat, protein and carbohydrate metabolism. The Office Action relies upon Betz-Brown for disclosing providing a plurality of predefined defect indicators. The Office Action points to “Fig 2 ‘eye disease’ ‘kidney disease’ and texts which further expand on their features” as providing the disclosure of this limitation. However, while the Betz-Brown reference provides a data input page (Fig. 2) including listing preexisting conditions, this reference provides no disclosure nor suggestion that these preexisting conditions are associated with any biological process. Indeed, it is clear that, rather than simulating the mechanisms underlying macronutrient metabolism and the development of diabetes, the Betz-Brown reference merely provides a risk analysis based on “a random number drawn from an appropriate distribution to determine whether (or how many) events of each kind occur.” (See, page S21, 2<sup>nd</sup> column). The range of likelihoods is based on a statistical incidence rate. Clearly this reference,

merely associates certain preexisting conditions with higher or lower rates of incidence – not with any biological process as in the present invention. Therefore, Betz-Brown does not disclose the limitation of providing a plurality of predefined defect indicators, where each defect indicator is associated with at least one biological process. Accordingly, Porumbescu and Betz-Brown when combined do not disclose the elements of the invention as claimed. Applicant requests withdrawal of the rejection.

**Claim 19** stands rejected under 35 U.S.C. § 103 as being rendered obvious by Porumbescu, in view of Betz-Brown, further in view of Official Notice Taken. While Applicant does not acquiesce to the Examiner’s Notice Taken, it is not necessary to respond because the underlying combination of Porumbescu and Betz-Brown does not disclose every limitation of claim 16, from which claim 19 depends. The underlying combination fails to disclose at least the limitations of a set of biological processes comprising a representation of two macronutrient metabolisms as defined by the claim, nor does the combination disclose a plurality of predefined defect indicators, each indicator associated with a biological process. The addition of an awareness of type 2 diabetes does not remedy the underlying lack of disclosure. Accordingly, Applicant requests withdrawal of the rejection.

**Claims 20, 25-28 and 35-38** stand rejected under 35 U.S.C. § 103 as being rendered obvious by Lehmann, *Diab. Nutr. Metab.* 1999, 12:380-387 (hereinafter Lehmann) in view of Porumbescu. The Office Action states that “As per claim 20, Lehmann discloses a diabetes simulator,” yet provides no basis for this assertion. Indeed, while Lehmann is listed as the base reference, the Office Action relies on Porumbescu for disclosing each of the elements recited in claim 20. Accordingly, Applicant is confused as to what Lehmann discloses that may teach or suggest any element of the claimed invention.

With regard to Porumbescu, in order to render a claim obvious under 35 U.S.C. § 103 a reference or combination of references must teach or suggest every limitation of the claimed invention. As discussed above in detail, Porumbescu does not disclose representation of the actual biological processes involved in macronutrient metabolism, providing simply a delayed

transition directly from fat or protein to glucose. As amended, claims 20, 25, 26, 27, and 28 recite specific biological processes, at least one of which must be included in a representation of fat or protein metabolism. Porumbescu does not disclose a representation of such biological processes. The Lehmann reference does not remedy this deficit. Indeed, in its discussion of diet (see page 383), Lehmann describes various aspects of nutrition that may impact diabetes, but that models were not capable of simulating at the time the Lehmann articles was written. For example, Lehmann indicates that

Modeling the effects of different types of food, eg rapidly absorbed carbohydrates (sugar, fruit juices, sweets, biscuits, *etc.*), slowly absorbed carbohydrates (vegetables, beans, pasta, *etc.*) and possibly alcohol should also be feasible in future generations of such programs.

This passage indicates that carbohydrate metabolism was not accurately simulated, but that certain improvements might be feasible at some time in the future.

Similarly, Lehmann acknowledges that not all foods have equivalent effect on glucose metabolism. The reference discusses glycemic index as a probable future inclusion in models of diabetes, but even this potential improvement is limited in its handling of protein and fat metabolism. As stated in Lehman:

The glucose absorption profile following the ingestion of, say, 50 g of carbohydrate in a hamburger, on its own may differ quite substantially from that when an identical quantity of carbohydrate is ingested as a meal of chips. Also the glucose absorption profile will be completely different, once again, if the hamburger and chips are eaten together. Quite what happens to glucose absorption when tomato sauce and vinegar are added to this meal no one quite knows.

Accordingly, rather than disclosing any model that can account for fat, protein and carbohydrate metabolism, as in the current invention, the Lehmann reference merely emphasizes the failure of prior models of glucose metabolism and diabetes to appropriately account for the digestion and absorption of fat and protein, as well as their associated hormonal effects. Thus the combination of Porumbescu and Lehmann does not disclose every element of the invention of



claims 20, 25-28 and 35-38 and therefore cannot render these claims obvious. Applicant requests withdrawal of the rejection

**Claims 21-23** stand rejected under 35 U.S.C. § 103 as being rendered obvious by Lehmann in view of Porumbescu and further in view of Betz-Brown. As discussed above, the Betz Brown reference merely associates certain preexisting conditions with higher or lower rates of incidence – not with any biological process as represented in the present invention. Therefore, Betz Brown does not disclose the limitation of providing a plurality of predefined defect indicators, where each defect indicator is associated with at least one biological process. Accordingly, the references when combined do not disclose the elements of the invention as claimed. Applicant requests withdrawal of the rejection.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 8 January 2007

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